UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. OLIVE STREET PHARMACY, LLC, and IRINA SHLAFSHTEYN, Defendants.	)	Case No. 4:21-cv-1165_

COMPLAINT

Plaintiff, the United States of America (United States), by its undersigned counsel, brings this action against Defendants Olive Street Pharmacy, LLC (Olive Street) and Irina Shlafshteyn (Shlafshteyn) seeking: (1) monetary penalties for violations of the Controlled Substances Act (CSA), 21 U.S.C. § 801, *et seq.*, (2) damages and monetary penalties for violations of the False Claims Act (FCA), 31 U.S.C. § 3729, *et seq.*, and (3) injunctive relief under the CSA, 21 U.S.C. § 843(f).

JURISDICTION AND VENUE

1. Jurisdiction is founded on the civil provisions of the CSA, 21 U.S.C. §§ 842(c)(1)(A), 843(f)(2), and 882(a); the FCA, 31 U.S.C. §§ 3729-3733; and under 28 U.S.C. §§ 1331, 1345, and 1355(a).

2. Venue is proper in the Eastern District of Missouri under 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a), because a substantial part of the events or omissions giving rise to the claims herein occurred in this District.

3. This Court has personal jurisdiction over Olive Street and Shlafshteyn (together, Defendants) because, at all relevant times, they transacted business in this District and Division in

Creve Coeur, Missouri, within St. Louis County.

PARTIES

4. Plaintiff is the United States. Acting through the Department of Health and Human Services (HHS) and, in turn, the Centers for Medicare & Medicaid Services (CMS), the United States administers (1) Medicare, a federally funded health insurance program for the elderly and disabled established by Title XVIII of the Social Security Act (SSA), 42 U.S.C. §§ 1395 *et seq.*; and (2) Medicaid, a federally funded grant program established by Title XIX of the SSA, 42 U.S.C. §§ 1396 *et seq.*, to enable States, including Missouri, to provide medical assistance and related services to indigent and low income persons. At all relevant times, the State of Missouri, through its Department of Social Services (DSS), MO HealthNet Division, administered the state-portion of the Medicaid program for indigent patients in Missouri on behalf of and at the direction of the United States.

5. Olive Street is a limited liability company formed and registered under the laws of the State of Missouri. It holds a license issued by the Missouri Board of Pharmacy, as well as a Drug Enforcement Administration (DEA) controlled substances registration. Olive Street operates as a retail pharmacy with its principal place of business at 10420 Old Olive Street Road, Suite 103, Creve Coeur, Missouri 63141.

6. At all relevant times, Shlafshteyn was a 25 percent owner and the managing employee of Olive Street. At all times relevant to this Complaint, Shlafshteyn operated, was a principal of, and exercised control over Olive Street. From in or about August 2014 to in or about September, 2021, Shlafshteyn also held a pharmacy technician license issued by the Missouri Board of Pharmacy. At all relevant times, Shlafshteyn worked as a pharmacy technician at Olive Street in addition to her role and duties as the pharmacy's managing employee. Shlafshteyn resides

in Saint Louis County, Missouri.

THE CONTROLLED SUBSTANCES ACT

7. The CSA and its implementing regulations set forth a comprehensive regulatory regime for the manufacture, distribution, and dispensing of controlled substances. Congress enacted the CSA to facilitate the availability of controlled substances for authorized medical use, while also preventing controlled substances from being diverted out of legitimate channels for illegal purposes. The CSA accordingly establishes a closed regulatory system under which it is unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA. 21 U.S.C. § 841(a)(1).

8. Under the CSA, controlled substances are categorized into five schedules based on several factors, including: the substance's medical use, potential for abuse, and safety or dependence liability.

9. Schedule II drugs are drugs with a "high potential for abuse" that may "lead to severe psychological or physical dependence" but nonetheless have a "currently accepted medical use in treatment." 21 U.S.C. § 812(b)(2). Examples of schedule II drugs include oxycodone (brand names OxyContin and Percocet), dextroamphetamine-amphetamine (brand name Adderall), and fentanyl (brand name Duragesic and Subsys).

10. Schedule III drugs are drugs with less potential for abuse than schedule II drugs but that nonetheless may still lead to "moderate or low physical dependence or high psychological dependence." 21 U.S.C. § 812(b)(3). Schedule III drugs also have "a currently accepted medical use in treatment." *Id.* Examples of schedule III drugs include buprenorphine (brand name Suboxone and Butrans) and acetaminophen with codeine.

11. Schedule IV drugs have a lower potential abuse than schedule III drugs but still

may lead to physical or psychological dependence when abused. 21 U.S.C. § 812(b)(4). Examples of schedule IV drugs include alprazolam (brand name Xanax), diazepam (brand name Valium), lorazepam (brand name Ativan), temazepam (brand name Restoril), zolpidem (brand name Ambien), and carisoprodol (brand name Soma).

12. The CSA requires pharmacies that distribute and dispense controlled substances to obtain a registration from the DEA. 21 U.S.C. § 822(a). A registered pharmacy is only permitted to distribute or dispense controlled substances "to the extent authorized by their registration and in conformity with" the CSA. 21 U.S.C. § 822(b).

13. Pharmacies may be registered to "dispense" controlled substances in Schedules II through V. 21 U.S.C. § 823(f). The CSA defines dispensing to mean delivering a controlled substance to an ultimate user (e.g., a patient) by, or pursuant to a lawful order of, a practitioner (i.e. a prescription). *See* 21 U.S.C. § 802(10). Distributing means delivering a controlled substance other than by dispensing or administering. *See id.* at § 802(11).

14. The agents and employees of a dispenser of controlled substances are not required to have a separate DEA registration "if such agent or employee is acting in the usual course of his business or employment." 21 U.S.C. § 822(c)(1).

15. Pharmacies cannot dispense a Schedule II drug to an ultimate end user without the written prescription of the practitioner, such as a physician. 21 U.S.C. § 829(a). Pharmacies cannot dispense Schedule III and Schedule IV controlled substances to an end user without a written or oral prescription from a practitioner. 21 U.S.C. § 829(b).

16. A prescription (written or oral) is legally valid under the CSA only if issued for "a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 C.F.R. § 1306.04(a). "An order purporting to be a prescription issued

not in the usual course of professional treatment . . . is not a prescription within the meaning and intent" of 21 U.S.C. § 829, "and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances." *Id.* "Person" is defined to include an individual, a corporation, a partnership, an association, and any other legal entity. 21 C.F.R. §§ 1300.01, 1306.02.

17. "The responsibility for proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 C.F.R. § 1306.04(a).

18. "A prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice and either registered individually or employed in a registered pharmacy . . . ." 21 C.F.R. § 1306.06.

TIRF REMS PROGRAM

19. Certain immediate-release fentanyl drugs have a particularly high potential for misuse, addiction, overdose, and other serious problems, including death. Due to these heightened risks, these drugs are available only through the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) program.

20. The TIRF REMS program is mandated by the Food and Drug Administration to ensure informed risk-benefit decisions before initiating TIRF treatment and to ensure appropriate use of TIRF medicines while patients are on treatment.

21. TIRF REMS products include Abstral (sublingual tablet), Actiq (lozenge), Fentora (buccal tablet), Lazanda (nasal spray), Onsolis (buccal soluble film), and Subsys (sublingual spray).

22. Prescribers of TIRF products are required to enroll in the TIRF REMS program, which, in turn, requires them to review TIRF educational materials and successfully complete a knowledge assessment.

23. Similarly, outpatient pharmacies must enroll in the TIRF REMS program before they are legally permitted to dispense TIRF products. For pharmacies, enrollment in the TIRF REMS program requires an authorized pharmacist to review TIRF educational materials and successfully complete a knowledge assessment.

24. Pursuant to the TIRF REMS program parameters, TIRF medicines are indicated only for the management of breakthrough pain in cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for underlying persistent cancer pain. Patients are considered opioid tolerant if, for at least one week, they have been taking: 60 milligrams of oral morphine per day; 25 micrograms of transdermal (patch) fentanyl per hour; 30 milligrams of oral oxycodone per day; 8 milligrams of oral hydromorphone per day; 25 milligrams of oral oxymorphone per day; 60 milligrams of oral hydrocodone per day; or an equianalgesic dose of another oral opioid daily.

25. The TIRF REMS program provides that patients must remain on around-the-clock opioids while using a TIRF product.

26. Additionally, the TIRF REMS program provides initial dosing instructions for patients starting TIRF therapy. For patients starting Subsys, the initial dosage is always 100 micrograms, unless the patient was previously taking certain amounts of Actiq.

27. TIRF medications are contraindicated for patients who are not opioid tolerant and for, among other things, the management of acute or postoperative pain including headache or migraine pain, dental pain, or acute pain in the emergency department.

THE MEDICAID PROGRAM

28. At all relevant times, the Missouri Medicaid program, jointly funded and operated by the federal and state governments, provided medical benefits to low income beneficiaries living in Missouri.

29. Medicaid provides coverage for prescription drugs only when used for medically accepted indications. 42 U.S.C. § 1396r-8(d)(1)(B)(i), (k)(3); 13 C.S.R. § 70-20.030.

30. At all relevant times, Olive Street was a participating Medicaid provider.

31. As a Medicaid provider, Olive Street agreed to and was required to comply with all the applicable rules and regulations of the Medicaid program, DSS, and HHS. As the managing employee of Olive Street, Shlafshteyn knew or should have known that Olive Street was not entitled to Medicaid payments for prescription drug reimbursement claims that did not comply with the applicable rules and regulations, including claims for prescription drugs that were not medically necessary.

32. Claims for Medicaid beneficiaries who purchased their prescription drugs at Olive Street were submitted for adjudication and payment to DSS and its fiscal intermediaries for processing and payment by Olive Street through its agents and employees, including Shlafshteyn.

THE MEDICARE PROGRAM

33. Congress established the Medicare program to provide health insurance coverage for people age 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 426, 426a.

34. The Medicare program consists of four parts: A, B, C, and D. Defendants submitted, or caused to be submitted, claims under Medicare Part D. Medicare Part D is an optional prescription drug benefit program. 42 U.S.C. § 1395w-101(a)(3)(A); 42 C.F.R. §

423.30(a).

35. Medicare Part D is based on a private market model. Medicare contracts with private entities known as Part D "Plan Sponsors" to administer prescription drug plans and deliver Part D, i.e. prescription, benefits to enrolled beneficiaries. Throughout the year, CMS makes monthly payments to the Part D Plan Sponsor for each Part D beneficiary enrolled in the plan. 42 C.F.R. § 423.329(a)(1).

36. By statute, all agreements between a Part D Plan Sponsor and HHS must include a provision whereby the Plan Sponsor agrees to comply with the standards and terms and conditions of payment governing the Part D program. 42 U.S.C. § 1395w-112. In turn, all subcontracts between Part D Plan Sponsors and downstream entities, such as pharmacies like Olive Street, obligate the downstream entity to comply with all applicable federal laws, regulations, and CMS instructions. 42 C.F.R. § 423.505(i)(4)(iv).

37. Medicare only covers drugs that are used for a medically accepted indication, which means a use that is approved under the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.*, or a use which is supported by one or more citations included or approved for inclusion in one of the specified compendia. 42 U.S.C. § 1395w-102(e)(1) & (e)(4); 42 U.S.C. § 1396r-8(g)(1)(B)(i) & (k)(6); 42 C.F.R. § 423.100.

38. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as for recreational use, are not for "medically accepted indications" and are therefore not covered Medicare Part D drugs. 42 U.S.C. § 1395w-102(e)(1).

39. Prescriptions for controlled substances that are not issued for a legitimate medical purpose, such as for recreational use, are not "valid prescriptions" and are therefore not covered Medicare Part D drugs. 42 C.F.R. § 423.104(h).

40. At all relevant times, Olive Street was a Medicare provider with various Part D Plan Sponsors.

41. As the managing employee of Olive Street, Shlafshteyn knew or should have known that Olive Street was not entitled to Medicare payments for prescription drug reimbursement claims that did not comply with the applicable rules and regulations, including claims for prescriptions drugs that were not medically necessary or were not dispensed pursuant to valid prescriptions.

42. Claims for Medicare Part D beneficiaries who purchased their prescription drugs at Olive Street were submitted for adjudication and payment to, ultimately, CMS and its fiscal intermediaries for processing and payment by Olive Street through its agents and employees, including Shlafshteyn.

FACTUAL BACKGROUND

43. As an outpatient retail pharmacy, Olive Street purchases, stores, and dispenses controlled substances. At all relevant times, Olive Street was registered with the DEA as a retail pharmacy to purchase, store, and dispense Schedules II-V controlled substances.

44. At all relevant times, Olive Street was registered with the TIRF REMS program to dispense TIRF products.

45. At all relevant times, as the managing employee of Olive Street, Shlafshteyn had the control and authority to effect Olive Street and its agents and employees' compliance with the CSA and the FCA.

46. Defendants failed to detect and address indicators of drug diversion, known in the pharmacy industry as "red flags," indicating that certain prescriptions were not legitimate.

47. For example, Defendants disregarded numerous instances in which the combined

total of daily "morphine milligram equivalents" for a patient grossly exceeded safe amounts.

48. A morphine milligram equivalent (MME) is an opioid potency value that uses a conversion factor to standardize the daily dose of an opioid into the equivalent dose of morphine. This provides a mechanism to assess the cumulative daily strength of all opioid prescriptions a patient is taking in a way that is standardized across different drugs, formulations, strengths, and dosage forms. For example, a 10-milligram dose of oxymorphone (a Schedule II drug) is equivalent in strength to approximately 30 milligrams of morphine. Thus, a 10-milligram dose of oxymorphone can be expressed as 30 MMEs.

49. The Centers for Disease Control and Prevention (CDC) recommends caution when using opioids at any dosage, carefully reassessing the risks and benefits of opioids when MMEs are 50 or higher, and avoiding or carefully justifying dosages of 90 MMEs or higher.

50. Defendants also dispensed prescriptions for opioids to patients at the same time as other medications that, when used in combination, are known to dangerously increase the opioid-produced euphoric high, as well as the risk of respiratory depression, cardiac depression, overdose, and death. Such medications are known as opioid "potentiators." Benzodiazepines, for example, are a class of drugs commonly known to be opioid potentiators; because of this, the CDC discourages use of benzodiazepines simultaneously with opioids.

51. Defendants routinely dispensed a combination of drugs colloquially known as the "holy trinity." The holy trinity is comprised of an opioid (such as oxycodone), a benzodiazepine (such as alprazolam), and a muscle relaxer (such as carisoprodol). The "new" holy trinity is similar but includes a stimulant (such as dextroamphetamine-amphetamine or phentermine) instead of a muscle relaxer. These combinations of drugs increase the euphoric, addictive, and dangerous effects of opioids, and prescriptions for these combinations are well known red flags in the

pharmacy industry.

52. Furthermore, Defendants filled prescriptions for Subsys, a TIRF drug subject to the TIRF REMS program requirements, despite knowing that the patients receiving Subsys did not meet various program requirements, including because they did not have breakthrough pain due to cancer.

53. The vast majority of the Subsys that Defendants dispensed was prescribed by Philip Dean (Dean), a neurologist who had an office located in Warrenton, Missouri, which is approximately 45 miles away from Olive Street. In 2018, Dean pled guilty to making false statements to the Medicare and Medicaid programs and to illegally distributing prescription opioids. He also admitted that he prescribed controlled substances (including Subsys, oxycodone, hydrocodone, Adderall, Duragesic, and codeine) to women with whom he had lived and with whom he had had personal relationships. *See generally United States v. Dean*, No. 4:18-CR-220-ERW (E.D. Mo. filed Mar. 15, 2018).

54. Shlafshteyn knew that Dean was having intimate relationships with at least one of the women for whom he was prescribing controlled substances, specifically, R.W. Despite this knowledge, Shlafshteyn and others at her direction continued to dispense the controlled substances prescribed by Dean to R.W. and to others.

55. The dispensing of a controlled substance in the face of the warning signals described above, without first ensuring the prescription was issued for a legitimate purpose by a practitioner acting in the usual course of professional practice, violates the CSA. A pharmacy that fills a prescription in the face of one or more of these red flags without taking sufficient steps to resolve the red flag(s) exceeds its authorization to dispense controlled substances under the CSA.

56. Submitting or causing the submission of claims to the Medicaid and/or Medicare

federal healthcare programs for medications (whether scheduled controlled substances or not) in the face of the warning signals described above, without first ensuring the prescriptions are valid and medically necessary, violates the FCA. Based on the red flags described above, Defendants knew that the prescriptions it filled were invalid and not used for a medically accepted indication, but nonetheless submitted or caused to be submitted claims for their reimbursement to the Medicaid and Medicare federal healthcare programs. If Medicaid and Medicare had known that these prescriptions were invalid, they would not have paid for them.

SPECIFIC CSA AND FCA VIOLATIONS

57. Defendants violated the CSA by dispensing controlled substances in violation of their corresponding responsibility and outside the usual course of pharmacy practice. They further violated the FCA when they knowingly submitted claims or caused Olive Street to submit claims for reimbursement for medically unnecessary and invalid prescriptions to the Medicaid and Medicare federal healthcare programs.

Patient J.D.

58. From in or about July 2015 to in or about April 2016, Defendants dispensed prescriptions written by Dean to Patient J.D. while disregarding red flags indicating that those prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

59. Defendants dispensed Subsys to Patient J.D. despite knowing that Patient J.D. did not have breakthrough pain due to cancer.

60. Defendants dispensed dangerous combinations of prescriptions to Patient J.D. In multiple instances, Defendants dispensed the holy trinity to Patient J.D. For example, on February 4, 2016, Defendants dispensed Duragesic 100 microgram per hour patches (an opioid), diazepam

5 milligram tablets (a benzodiazepine), and tizanidine 4 milligram tablets (a muscle relaxer) for Patient J.D. Furthermore, on the same date, Defendants dispensed a prescription for gabapentin 300 milligram capsules to Patient J.D. Gabapentin is a known opioid potentiator.

61. On another occasion, Defendants dispensed prescriptions for Patient J.D. that grossly exceeded CDC guidelines. Specifically, on January 11, 2016, Defendants dispensed, among other things, Duragesic 100 microgram per hour patches, hydrocodone-acetaminophen 10-325 milligram tablets (one table four times daily), and Subsys 1,200 microgram spray (one dose up to six times per day). The combined MMEs for these prescriptions totaled 1,576, or approximately 17.5 times the level of MMEs that the CDC recommends avoiding. Dispensing these prescriptions put Patient J.D. at extremely high risks for overdose and death.

62. Additionally, the January 11, 2016 combination that Defendants dispensed contained two short-acting narcotic painkillers: Subsys and hydrocodone. The presentment of more than one prescription for a short-acting narcotic painkiller is a red flag in the pharmacy industry, and taking a short-acting narcotic painkiller in combination with another one produces heightened risks of an adverse event, including possible respiratory failure.

63. The chart attached as Exhibit 1 contains Schedule II and Schedule IV drugs, plus gabapentin and muscle relaxers, that Defendants dispensed to Patient J.D. from July 2015 to April 2016. Each of the drugs listed in the chart in Exhibit 1 is a prescription drug under the FDCA.

64. All but two prescriptions in Exhibit 1 were billed to the Medicare federal healthcare program, the Medicaid federal healthcare program, or both, thereby implicating FCA liability, as indicated.

65. Based on the red flags described above, Defendants knew that the prescriptions listed in Exhibit 1 were not used for a medically accepted indication and lacked a legitimate

medical purpose. If Medicaid and Medicare had known that these prescriptions were invalid, they would not have paid for them.

66. Defendants knowingly dispensed these drugs pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1), and 21 C.F.R. § 1306.04.

67. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

Patient M.R.

68. From in or about October 2015 to in or about August 2017, Defendants dispensed prescriptions written by Dean for Patient M.R. while disregarding red flags indicating that those prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

69. Defendants dispensed Subsys to Patient M.R. despite knowing that Patient M.R. did not have breakthrough pain due to cancer. In fact, the International Classification of Diseases (ICD)-10 code used to support the Subsys prescriptions for Patient M.R. was M25.571, or pain in the right ankle and joints of right foot.

70. Defendants failed to ensure that Patient M.R. was opioid tolerant before dispensing Subsys to Patient M.R., and the first Subsys prescription that Defendants dispensed to Patient M.R. was 400 micrograms in strength, or four times the maximum initial dosage. Defendants did not take steps to ensure that Patient M.R. had previously taken lower amounts of Subsys or the requisite amounts of Actiq that could justify dispensing 400 micrograms of Subsys to Patient M.R.

71. Additionally, Defendants dispensed dangerous combinations of prescriptions to

Patient M.R. For example, Defendants dispensed prescriptions for multiple long-acting narcotic painkillers at the same time, and at times dispensed opioids at the same time as a benzodiazepine, or with a muscle relaxer, or with a stimulant. Such combinations of drugs produce heightened risks of an adverse event, including possible respiratory failure. Dangerous combinations such as those dispensed to Patient M.R. are red flags because they are sought after by those who seek prescriptions for the non-medical purpose of increasing the euphoric effects of opioids.

72. In multiple instances, the combined MMEs of the prescriptions that Defendants dispensed to Patient M.R. were dangerously high. For example, on some occasions, Defendants dispensed (among other things) both OxyContin 20 milligram tablets (to be taken twice a day) and fentanyl 100 microgram per hour patches to Patient M.R. These two medications alone amount to a total of 300 MMEs daily: over three times the level of daily MMEs that the CDC recommends avoiding.

73. On another occasion—in October 2015—Defendants dispensed opioids (namely, OxyContin, oxycodone, and Subsys) that amounted to 468 MMEs per day: over five times the maximum dosage that the CDC recommends avoiding.

74. The chart attached as Exhibit 2 contains Schedule II-IV drugs, plus non-scheduled muscle relaxers, that Defendants dispensed to Patient M.R. from October 2015 to August 2017. Each of the drugs listed in the chart in Exhibit 2 is a prescription drug under the FDCA.

75. All but two prescriptions in Exhibit 2 were billed to the Medicaid federal healthcare program, thereby implicating FCA liability, as indicated.

76. Based on the red flags described above, Defendants knew that the prescriptions listed in Exhibit 2 were not used for a medically accepted indication and lacked a legitimate medical purpose. If Medicaid had known that these prescriptions were invalid, it would not have

paid for them.

77. Defendants knowingly dispensed these drugs pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1), and 21 C.F.R. § 1306.04.

78. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

Patient T.K.

79. From in or about October 2015 to in or about February 2016, Defendants dispensed prescriptions written by Dean to Patient T.K. while disregarding red flags indicating that those prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

80. Defendants dispensed Subsys to Patient T.K. despite knowing that Patient T.K. did not have breakthrough pain due to cancer. In fact, the ICD-10 codes used to support the Subsys prescriptions for Patient T.K. were E11.44 (type 2 diabetes with diabetic amyotrophy), M54.7 (panniculitis affecting regions of neck and back, lumbosacral region), F51.09 (insomnia not due to a substance or known physiological condition), and M99.53 (intervertebral disc stenosis of neural canal of lumbar region).

81. Defendants failed to ensure that Patient T.K. was opioid tolerant before dispensing Subsys to Patient T.K., and the first Subsys prescription that Defendants dispensed to Patient T.K. was 400 micrograms in strength, or four times the maximum initial dosage. Defendants did not take steps to ensure that Patient T.K. had previously taken lower amounts of Subsys or the requisite amounts of Actiq that could justify dispensing 400 micrograms of Subsys to Patient T.K.

82. Defendants also dispensed other short-acting narcotic painkillers, such as oxycodone, to Patient T.K. at the same time as Subsys. The presentment of more than one prescription for a short-acting narcotic painkiller is a red flag in the pharmacy industry, and taking a short-acting narcotic painkiller in combination with another one produces heightened risks of an adverse event, including possible respiratory failure.

83. The levels of MMEs that Defendants dispensed to Patient T.K. were dangerously high. For example, in December 2015, Defendants dispensed oxycodone and Subsys to Patient T.K., for a total of 621 MMEs daily, or nearly seven times the level of daily MMEs that the CDC recommends avoiding.

84. By disregarding all of these red flags, Defendants put Patient T.K. at risk of overdose.

85. The chart attached as Exhibit 3 contains Schedule II and Schedule IV drugs that Defendants dispensed to Patient T.K. from October 2015 to February 2016. Each of the drugs listed in the chart in Exhibit 3 is a prescription drug under the FDCA.

86. All prescriptions in Exhibit 3 were billed to the Medicaid federal healthcare program, thereby implicating FCA liability, as indicated.

87. Based on the red flags described above, Defendants knew that the prescriptions listed in Exhibit 3 were not used for a medically accepted indication and lacked a legitimate medical purpose. If Medicaid had known that these prescriptions were invalid, it would not have paid for them.

88. Defendants knowingly dispensed these drugs pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1), and 21 C.F.R. § 1306.04.

89. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

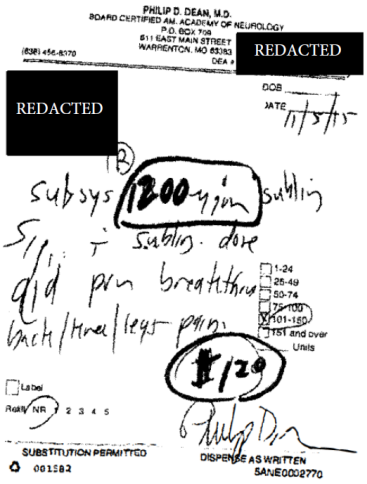
Patient S.T.

90. From in or about July 2015 to in or about February 2017, Defendants dispensed prescriptions written for Patient S.T. while disregarding red flags indicating that those prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. All but one of these prescriptions were written by Dean.

91. Defendants dispensed Subsys to Patient S.T. despite knowing that Patient S.T. did not have breakthrough pain due to cancer.

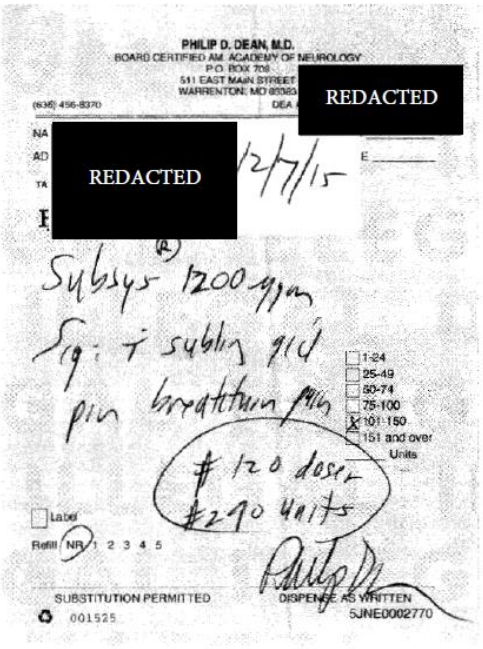
92. In some instances, Defendants dispensed Subsys prescriptions to Patient S.T. despite clear indications that the written prescriptions had been tampered with in various ways. For instance, the strength and quantity of a November 5, 2015 Subsys prescription that Defendants dispensed to Patient S.T. were clearly manipulated by writing over the original strength and quantity with black marker:

November 5, 2015 Subsys Prescription

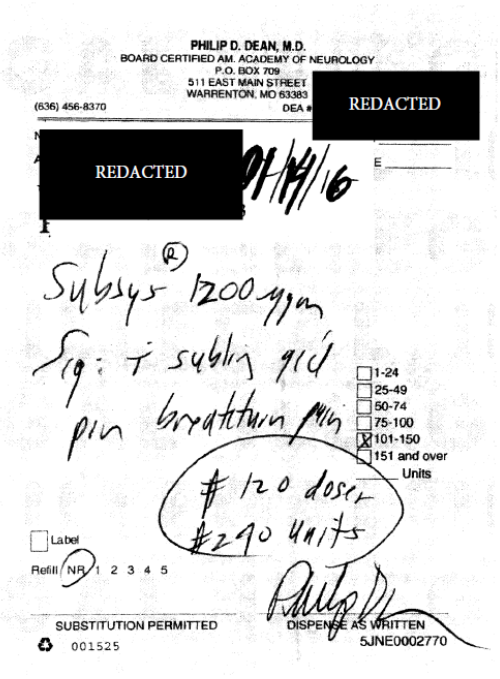


93. In another instance, the date of a Subsys prescription that Defendant dispensed to Patient S.T. on January 14, 2016 was clearly changed by writing over the original date with black marker; a review of Patient S.T.'s file reveals that the original version of that prescription was dated over a month earlier, on December 7, 2015, and had already been dispensed by Defendants:

Subsys Prescription Dated December 7, 2015



Subsys Prescription Dispensed on January 14, 2016



94. Defendants dispensed dangerous combinations of prescriptions for Patient S.T. In multiple instances, Defendants dispensed OxyContin (an opioid), chlordiazepoxide (a benzodiazepine), and carisoprodol (a muscle relaxer) to Patient S.T.; by doing so, Defendants dispensed the holy trinity. Oftentimes, Defendants would also fill a prescription for gabapentin at or around the same time as the holy trinity, such that Patient S.T. could be taking all four medications at one time. Gabapentin is a known opioid potentiator.

95. Defendants also dispensed dangerous levels of MMEs for Patient S.T. For example, in December 2015, Defendants dispensed OxyContin 20 milligram tablets (one tablet twice daily) and Subsys 1,200 microgram spray (one dose up to four times daily), for a total of 924

MMEs daily: over ten times the maximum level of daily MMEs that the CDC recommends avoiding.

96. The chart attached as Exhibit 4 contains Schedule II-IV drugs that Defendants dispensed to Patient S.T. from July 2015 to February 2017. Each of the drugs listed in the chart in Exhibit 4 is a prescription drug under the FDCA.

97. Most of the prescriptions in Exhibit 4 were billed to the Medicaid federal healthcare program, thereby implicating FCA liability, as indicated.

98. Based on the red flags described above, Defendants knew that the prescriptions listed in Exhibit 4 were not used for a medically accepted indication and lacked a legitimate medical purpose. If Medicaid had known that these prescriptions were invalid, it would not have paid for them.

99. Defendants knowingly dispensed these drugs pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1), and 21 C.F.R. § 1306.04.

100. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

Patient E.H.

101. From in or about October 2015 to in or about February 2018, Defendants dispensed prescriptions written for Patient E.H. while disregarding red flags indicating that those prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. According to Olive Street's records, the prescribing physician for these prescriptions was Stanley Librach (Librach). On or about February 13, 2020,

a federal grand jury indicted Librach for, among other things, illegally prescribing controlled substances in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2. *See generally United States v. Ali, et al.*, No. 4:20-CR-00098-HEA (E.D. Mo. filed Feb. 13, 2020).

102. On multiple occasions, Defendants dispensed oxycodone 30 milligram tablets and phentermine 37.5 milligram tablets at the same time to Patient E.H. Thirty milligrams is the highest available strength of short-acting oxycodone; a prescription for oxycodone 30 milligrams is in itself a red flag, particularly where, as here, it is presented to the pharmacy by the same patient on multiple occasions. Phentermine is a stimulant and an opioid potentiator. A prescription for phentermine that accompanies a prescription for oxycodone is another red flag, particularly where, as here, it is presented to the pharmacy by the same patient on multiple occasions.

103. Defendants knew that prescriptions naming Librach as the prescribing physician should be carefully monitored and filled only after verifying that they were issued for a legitimate medical reason.

104. Each time Defendants dispensed an oxycodone 30 milligram prescription for Patient E.H., the cumulative daily MME total was 135, well above the level of daily MMEs that the CDC recommends avoiding. This continued for over two years.

105. Despite all of these red flags presented by Patient E.H.'s prescriptions, Defendants continued to dispense them without resolving the red flags.

106. The chart attached as Exhibit 5 contains oxycodone and phentermine prescriptions that Defendants dispensed to Patient E.H. from October 2015 to February 2018. Each of the drugs listed in the chart in Exhibit 5 is a prescription drug under the FDCA.

107. None of the prescriptions listed in Exhibit 5 were billed to a federal healthcare program; thus, all of the prescriptions in Exhibit 5 implicate CSA liability only, as indicated.

108. Defendants knowingly dispensed these drugs pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1), and 21 C.F.R. § 1306.04.

109. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

Patient H.L.

110. From in or about July 2015 to in or about March 2018, Defendants dispensed prescriptions written for Patient H.L. while disregarding red flags indicating that those prescriptions were not issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

111. In multiple instances, Defendants dispensed the holy trinity, the new holy trinity, or a combination of both for Patient H.L.

112. For example, in April 2017, Defendants dispensed oxycodone (an opioid), alprazolam (a benzodiazepine), and amphetamine salts (a stimulant) to Patient H.L.; by doing so, Defendants dispensed the new holy trinity.

113. Other times—in February 2017, for example—Defendants dispensed this same combination of drugs, with the addition of baclofen, a muscle relaxer and opioid potentiator. The combination of oxycodone (an opioid), alprazolam (a benzodiazepine), and baclofen (a muscle relaxer) constitutes the holy trinity, in addition to the new holy trinity being fulfilled by the amphetamine salts (stimulant), simultaneously.

114. Dispensing these combinations was particularly problematic given that the amphetamine salts and alprazolam that Defendants dispensed to Patient H.L. were prescribed by a

physician from a completely different medical practice than the practice from which the other two prescriptions originated. Where, as here, a patient presents prescriptions for suspect drug combinations from different providers, the pharmacy—as the sole medical provider with knowledge of the combination—has an even higher duty to ensure that the drug combination is safe and that the prescriptions are being written for valid medical necessities. The pharmacy has a duty to ensure that the different providers are aware of each other's prescriptions and the drug interactions that may occur. Defendants did not fulfill these duties.

115. Additionally, when Defendants dispensed baclofen to Patient H.L., the prescriber, according to Olive Street records, was Librach. Defendants knew that prescriptions naming Librach as the prescribing physician should be carefully monitored and filled only after verifying that they were issued for a legitimate medical reason.

116. When Defendants dispensed oxycodone to Patient H.L., the prescriber of record was typically Asim Ali (Ali). Like Librach, Ali was indicted by a federal grand jury on or about February 13, 2020, for, among other things, illegally prescribing controlled substances in violation of 21 U.S.C. § 841(a)(1) and 18 U.S.C. § 2. *See generally United States v. Ali, et al.*, No. 4:20-CR-00098-HEA (E.D. Mo. filed Feb. 13, 2020).

117. Each time Defendants dispensed an oxycodone prescription to Patient H.L., the cumulative daily MME total was 120, well above the level of daily MMEs that the CDC recommends avoiding.

118. Despite all of these red flags presented by Patient H.L.'s prescriptions, Defendants continued to dispense them without resolving the red flags.

119. The chart attached as Exhibit 6 contains Schedule II and Schedule IV drugs, plus muscle relaxers, that Defendants dispensed Patient H.L. from July 2015 to March 2018. Each of

the drugs listed in the chart in Exhibit 6 is a prescription drug under the FDCA.

120. All prescriptions in Exhibit 6 were billed to the Medicaid federal healthcare program, and some were also paid for by the Medicare federal healthcare program, implicating FCA liability, as indicated.

121. Based on the red flags described above, Defendants knew that the prescriptions listed in Exhibit 6 were not used for a medically accepted indication and lacked a legitimate medical purpose. If Medicare and Medicaid had known that these prescriptions were invalid, they would not have paid for them.

122. Defendants knowingly dispensed these drugs pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1), and 21 C.F.R. § 1306.04.

123. Defendants dispensed these controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

Count I:
Civil Penalties for Unlawful Dispensing of
Controlled Substances under the Controlled Substances Act

124. The United States realleges and incorporates by reference Paragraphs 1 through 123 of the Complaint as if fully set forth herein.

125. Defendants knowingly dispensed controlled substances pursuant to prescriptions that were issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1), and 21 C.F.R. § 1306.04.

126. Defendants dispensed controlled substances while acting outside the usual course of the professional practice of pharmacy and not in compliance with their "corresponding

responsibility" in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. §§ 1306.04 and 1306.06.

127. As a result of the foregoing, Defendants are liable to the United States for a civil penalty in an amount of not more than $25,000 for each violation occurring on or before November 2, 2015, and not more than $67,627 for each violation occurring after November 2, 2015, pursuant to 21 U.S.C. § 842(c)(1)(A) and 28 C.F.R. § 85.5.

Count II:
False or Fraudulent Claims to Medicaid and
Medicare for Prescription Drugs in Violation of the False Claims Act

128. The United States realleges and incorporates by reference Paragraphs 1 through 127 of the Complaint as if fully set forth herein.

129. Defendants knowingly, or with reckless disregard, presented, or caused to be presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

130. Specifically, Defendants submitted, or caused to be submitted, requests for payment to Medicaid and to Medicare Part D Plan Sponsors for controlled substances and other medications, as specified above, that were invalid and not dispensed for a legitimate medical purpose.

131. Because of Defendants' acts, the United States suffered damages in an amount to be determined at trial, and therefore is entitled to treble damages under the FCA, plus civil penalties of not less than $5,500 and up to $11,000 per violation for violations that occurred on or before November 2, 2015, and of not less than $11,665 and up to $23,331 for violations that occurred after that date. 31 U.S.C. § 3729(a); 28 C.F.R. § 85.5.

Count III:
Injunctive Relief Pursuant to
the Controlled Substances Act

132. The United States realleges and incorporates by reference Paragraphs 1 through 131 of the Complaint as if fully set forth herein.

133. Defendants knowingly dispense controlled substances pursuant to prescriptions that are issued without a legitimate medical purpose and outside the usual course of professional practice in violation of 21 U.S.C. §§ 829(a) and (b), and 842(a)(1), and 21 C.F.R. § 1306.04.

134. Defendants dispense controlled substances while acting outside the usual course of the professional practice of pharmacy in violation of 21 U.S.C. § 842(a)(1) and 21 C.F.R. § 1306.06.

135. Based on the foregoing, unless enjoined by this Court pursuant to 21 U.S.C. §§ 843(f) and 882(a), Defendants will continue to violate the Controlled Substances Act in the manner set forth above.

DEMAND FOR RELIEF

WHEREFORE, the United States respectfully requests that:

A. As to Count I, judgment be entered in favor of the United States and against Defendants for civil penalties under the CSA, plus interest, costs, and any and all relief that the Court deems just and proper.

B. As to Count II, judgment be entered in favor of the United States and against Defendants for treble damages and civil penalties under the FCA, plus interest, costs, and any and all relief that the Court deems just and proper.

C. As to Count III, an order be entered for appropriate injunctive relief pursuant to 21 U.S.C. §§ 843(f) and 882(a).

Dated: September 28, 2021

Respectfully submitted,

SAYLER A. FLEMING

UNITED STATES ATTORNEY

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